

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandra, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE ATTORNEY DOCKET NO. FIRST NAMED INVENTOR CONFIRMATION NO. 09/802,152 03/08/2001 Hideji Tajima 10287.41 6205 27683 7590 **EXAMINER** 11/05/2003 HAYNES AND BOONE, LLP FORMAN, BETTY J 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202 **ART UNIT** PAPER NUMBER 1634 **DATE MAILED: 11/05/2003**

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	A	pplicant(s)
Office Action Summary		09/802,152	09/802,152 TAJIMA, HIDEJI	
		Examiner	niner Art Unit	
		BJ Forman	16	534
Period	The MAILING DATE of this communication app for Reply	pears on the cover	sheet with the corr	espondence address
TH E at - If - If - F - A	EHORTENED STATUTORY PERIOD FOR REPLY E MAILING DATE OF THIS COMMUNICATION. extensions of time may be available under the provisions of 37 CFR 1.13 fter SIX (6) MONTHS from the mailing date of this communication. The period for reply specified above is less than thirty (30) days, a reply NO period for reply is specified above, the maximum statutory period value to reply within the set or extended period for reply will, by statute my reply received by the Office later than three months after the mailing arned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, howe y within the statutory mini will apply and will expire So, cause the application to	ver, may a reply be timely formum of thirty (30) days will IX (6) MONTHS from the robecome ABANDONED (3	filed I be considered timely. mailing date of this communication. IS U.S.C. § 133).
1)[∑	Responsive to communication(s) filed on 12 A	August 2003 .		
2a)[☐ This action is FINAL . 2b)☑ Th	is action is non-fir	al.	
3)[Disp s	Since this application is in condition for allowated closed in accordance with the practice under sition of Claims	•	•	
4)[Claim(s) <u>1-22, 24-25, 27-49</u> is/are pending in t	the application.		
	4a) Of the above claim(s) <u>8-21,30-35 and 39-49</u>	9 is/are withdrawn	from consideration	n.
5)[Claim(s) is/are allowed.			
6)[2	Claim(s) <u>1-7,22,24,25,27-29 and 36-38</u> is/are r	ejected.		
7)[Claim(s) is/are objected to.			
8)[Claim(s) are subject to restriction and/or	r election requiren	nent.	
	ation Papers	·		
9)[2	The specification is objected to by the Examine	r.		
10)[☐ The drawing(s) filed on is/are: a)☐ accep	oted or b) objecte	d to by the Examin	er.
	Applicant may not request that any objection to the	e drawing(s) be held	in abeyance. See 3	37 CFR 1.85(a).
11)[The proposed drawing correction filed on	is: a)∏ approve	d b) disapproved	by the Examiner.
	If approved, corrected drawings are required in rep	oly to this Office acti	on.	
12)[The oath or declaration is objected to by the Exa	aminer.		
Priority	under 35 U.S.C. §§ 119 and 120			
13)[Acknowledgment is made of a claim for foreign	priority under 35	U.S.C. § 119(a)-(d	l) or (f).
á	a) All b) Some * c) None of:			
	1. Certified copies of the priority documents	s have been recei	ved.	
	2. Certified copies of the priority documents			No
*	3. Copies of the certified copies of the prior application from the International Bur See the attached detailed Office action for a list of the control of the certified copies of the prior and the certified copies of the prior application for a list of the certified copies of the prior application for a list of the certified copies of the prior application for a list of the certified copies of the prior application from the line prior application from the	ity documents have reau (PCT Rule 1)	e been received in 7.2(a)).	
	Acknowledgment is made of a claim for domestic	·		n a provisional application)
	a) The translation of the foreign language pro-	visional applicatio	n has been receive	ed.
ارت Attachme	Acknowledgment is made of a claim for domesticent(s)	o priority under 35	0.3.0. 99 120 and	u/OF 121.
1)	tice of References Cited (PTO-892) tice of Draftsperson's Patent Drawing Review (PTO-948) Drmation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 🗆		O-413) Paper No(s) nt Application (PTO-152)

Application/Control Number: 09/802,152 Page 2

Art Unit: 1634

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 August 2003 has been entered.

Status of the Claims

2. This action is in response to papers filed 12 August 2003 in which claims 1, 3, 5, 22, 25, 28, 37, 38 were amended and Claims 23 and 26 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 12 March 2003 are maintained as reiterated below. Rejections not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below.

In the second paragraph of page 15, Remarks/Argument, Applicant incorrectly states the status of the claims. The correct status is as follows:

Claims 23 and 26 are canceled.

Claims 8-21, 30-35 and 39-49 are withdrawn from prosecution.

Claims 1-7, 22, 24-25, 27-29 and 36-38 are under prosecution.

Additional Comments

3. Claims 1-7 are drawn to a product i.e. integrated support. The claims repeatedly recite functional language e.g. "substances being fixed", "base member being integrated", "wherein said base member is rolled in such a way that the base member either enables or prevents expansion while bringing side portion thereof into contact with each other or while maintaining a spacing or while sandwiching an auxiliary member", "markings are attached to said base member for identifying the chemical structure of said substances for detection". functional language describes processes of making the support and/or processes of using the support. For example, the recitation "markings are attached" describes a method step of attaching markings but does not describe a structural limitation or component of the support. A structural limitation would describe or define components of the support. A structural limitation could be recites as e.g. the support further comprising markers. Furthermore, the recitation "for identifying the chemical structure of said substances for detection" describes an intended use for the support. However, the intended use does not describe or define structural limitations or components of the support.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

The courts have further stated that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior

Art Unit: 1634

art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Because the courts have stated that products must be defined by their structural components, the recitations of intended use and/or process of making do not define the claimed products over the prior art.

It is suggested that the claims be written to clearly define and describe the structural components of the integrated support.

Specification

4. The abstract of the disclosure is objected to because the Abstract consists of two paragraphs and therefore does not comply with the requirements of MPEM § 608.01(b).

Correction is required.

Reiterated from previous Office Action

5. The amendment filed 8 August 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The specification has been amended to insert a first paragraph which cross-references and incorporates by reference the provisional application to which the instant application

Art Unit: 1634

claims priority. The application, as filed, claimed priority to the provisional application.

However, the application, as filed, did not incorporate the provisional application by reference.

Therefore, the incorporation by reference constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Acti n.

Claim Objections

6. Claims 24-25 and 27-29 objected to because they depend from canceled Claim 23.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- Claims 22, 24-25, 27-29 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 8. Claims 22, 24-25, 27-29 and 36 are indefinite in Claim 22 because the claim recites method steps of making an integrated support comprising 1) making a base member; 2) positioning and fixing substances for detection...on said base member; 3) selecting the shape of said base member; 4) rolling the base member; and 5) selecting the location of substances for detection. However, it is completely unclear how the recited steps result in an integrated

Art Unit: 1634

support. For example, the steps of 1) making a base member and 3) selecting a shape of a base member are recited as independent steps and furthermore separated by 2) positioning and fixing substances. Therefore, it is unclear what is encompassed by step 1, making a base member. Similarly, step 2) positioning and fixing substances and 5) selecting the location of substances for detection both appear to be steps of positioning the substances. Therefore, it is unclear what is encompassed by step 2 that differs from step 5 and it is further indefinite how step 5 further limits step 2.

In amending the claim, Applicant has not pointed to a passage in the specification to support amendments. As such, Applicant has not provided guidance for interpretation of the claim as amended. Therefore, for purposes of examination, Claim 22 is interpreted to encompass the same scope as the previously presented claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1634

10. Claims 1-6, 22-29 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Stimpson (U.S. Patent No. 6,037,186, filed 16 July 1997).

Regarding Claim 1, Stimpson discloses an integrated support comprising at least one base member, a variety substances for detection of predetermined chemical structure fixed side by side (and at intervals) along the length of the base member wherein said base member is integrated to from a cylinder whereby a fixed location of each substance identifies the chemical structure wherein the shape of the base member is selected from a rod shape and a long and slender shape and wherein each substance is fixed at a location selected from the group consisting of on the surface of the base member and channels in the base member (Column 3, line 46-Column 5, line 39; Column 12, line 42-Column 13, line 67; and Fig. 2A-E).

Regarding Claim 2, Stimpson discloses the integrated support wherein the material of said base member is selected from a porous material, a fibrous material or an impregnating material (Column 10, lines 16-57 and Column 14, lines 8-10 and 45-48).

Regarding Claim 3, Stimpson discloses the support wherein said base member is arranged in such a way that the base member either prevents or enables expansion while bringing side portions into contact with each other or maintaining spacing or sandwiching (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C).

Regarding Claim 4, Stimpson discloses the support wherein markings are attached to said base member for identifying the chemical structure (Column 7, lines 49-60 and Column 13, lines 18-20 and 40-41).

Regarding Claim 5, Stimpson discloses the support further comprising a binding section (i.e. adhesive) for binding said base member and/or an auxiliary member in such a way that the auxiliary is either releasable or non-releasable (i.e. when the support is rod shaped the rods are arranged in a sheath which secures the rod arrangement, Column 13, lines 42-43 and when the support is a long and slender shape the base member is rolled the integrity of the rolled base member is maintained Column 6, lines 2-6 and where either base member is

Art Unit: 1634

secured with an adhesive which provides a solid integrated support i.e. non-releasable Column 5, lines 56-61).

Regarding Claim 6, Stimpson discloses the support wherein said binding section is an adhesive portion for bonding side portion of said base member (Column 5, lines 48-65).

Regarding Claim 22, Stimpson discloses a method of manufacturing an integrated support comprising a positioning step for positioning and fixing substances for detection at predetermined locations on at least one base member at intervals (Fig. 2) and an integration step for rolling said base member to give integration so that a surface in which the substances for detection are fixed and the location of the substances for detection is selected from the surface of the base member and in the base member when the base member is made from a porous material (Column 9, lines 18-39; Column 10, lines 16-57; and Column 12, line 56-Column 13, line 59).

Regarding Claim 23, Stimpson discloses the method wherein said base member has a rod shape or a long and slender shape (Column 3, lines 36-46).

Regarding Claim 24, Stimpson discloses the method wherein said positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member (Column 7, lines 19-28 and Column 9, lines 18-42).

Regarding Claim 25, Stimpson discloses the method wherein said base member is arranged in such a way that the base member either prevents or enables expansion while bringing side portions into contact with each other or maintaining spacing or sandwiching (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C).

Regarding Claim 26, Stimpson discloses the method wherein said base member is formed as a thin sheet said substances for detection are positioned on the base member in lines which do not intersect or contact each other and said integration step involves rolling in a way that either prevents or enables expansion (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C) and wherein a cutting step is provided following integration in which the base member

Art Unit: 1634

is sliced thinly to form a plurality of integrated supports in which the cross-sectional surface functions as a layer surface (Column 6, line 64-Column 7, line 6; Column 9, lines 8-17; Column 12, lines 65-67; Column 13, lines 26-31 and 60-61 and Fig. 2).

Regarding Claim 27, Stimpson discloses the method wherein said positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member (Column 7, lines 19-28 and Column 9, lines 18-42) wherein said base member is made from a porous material, a fibrous material or an impregnating material (Column 9, lines 18-39 and Column 10, lines 16-57).

Regarding Claim 28, Stimpson discloses the method wherein in the integrating step, said base member and/or an auxiliary member in such a way that the auxiliary is either releasable or non-releasable (i.e. when the support is rod shaped the rods are arranged in a sheath which secures the rod arrangement, Column 13, lines 42-43 and when the support is a long and slender shape the base member is rolled the integrity of the rolled base member is maintained Column 6, lines 2-6 and where either base member is secured with an adhesive which provides a solid integrated support i.e. non-releasable Column 5, lines 56-61).

Regarding Claim 29, Stimpson discloses the method wherein in the positioning step said substances are fixed and supported onto said base member by drying i.e. placed on paper towel (Example 6, Column 16, lines 18-23).

Regarding Claim 36, Stimpson discloses a method of using the integrated medium of Claim 22 wherein passing a heating fluid (sample) through the integrated support, the integrated support is heated (Example 5, Column 15, line 37-Column 16, line 13).

Regarding Claim 37, Stimpson discloses a method of using an integrated medium of Claim 1 comprising: a processing step for detecting a substance using an integrated support and a measuring step for conducting measurements of an optical state on an outside layer surface with the integrated support (Examples 5-6; Column 15, line 37-Column 16, line 30; and Claims 10-11).

Regarding Claim 38, Stimpson discloses the method wherein the measuring involves identification of an absolute location on the surface i.e. address-specific position is detected and measured (Examples 5-6; Column 15, line 37-Column 16, line 30; and Claim 10 (e)).

Response to Arguments

11. Applicant argues that in contrast to the instant invention wherein the base member is a cylinder, prism, cone or pyramid, Stimpson is limited to substances fixed for detection as fixed, flat planes as illustrated in Fig 2E. The argument has been considered but is not found persuasive because as illustrated in Fig. 1A, the base member of Stimpson is a cylinder.

Applicant argues that the instant invention has advantages over that of Stimpson e.g. requires smaller sample volume thereby providing efficient detection. The argument has been considered but is not relevant to the instant claims because the claims are drawn to an integrated support the limitations of which are taught by Stimpson.

Regarding Claim 22, Applicant argues that the instantly claimed method of making the support does not require the cutting of Stimpson and therefore the instant invention minimizes loss of detectable substances. The argument has been considered but is not found persuasive because the claim is drawn to a method "comprising" the steps of making, positioning, selecting, rolling and selecting. The open language "comprising" encompasses any additional steps taught by Stimpson. Furthermore, as stated above in ¶ 8, Claim 22 is indefinite and confusing. However, for purposes of examination, the claim is interpreted as encompassing a scope similar to that of the previously presented claim.

Art Unit: 1634

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson (U.S. Patent No. 6,037,186, filed 16 July 1997) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 7, Stimpson teaches an integrated support comprising at least one base member, a variety substances for detection of predetermined chemical structure fixed side by side (and at intervals) along the length of the base member wherein said base member is integrated whereby a fixed location of each substance identifies the chemical structure wherein the shape of the base member is selected from a rod shape and a long and slender shape, wherein the means for integration is arranging (a rod member) or rolling (a long and slender member) and wherein each substance is fixed at a location consisting of on the surface of the base member and channels in the base member (Column 3, line 46-Column 5, line 39; Column 12, line 42-Column 13, line 67; and Fig. 2A-E) wherein the integrated support comprises a linear member (cylindrical support) embedded inside the base member (Column 6, lines 59-63 and Fig. 2 #240) and Stimpson teaches that the support is exposed to fluids of differing temperatures (Example 5, Column 15, line 37-Column 16, line 13) but Stimpson is silent regarding the thermal properties (i.e. homoiothermal) of the embedded member. Lipshutz teaches a similar integrated support comprising a rod shaped and/or long and slender shaped base member (i.e. capillaries Column 11, lines 59-64) and a variety of substances fixed side by side along the length of said base member wherein said base member is arranged to give integration and wherein a thermal member is embedded inside said base member for

Application/Control Number: 09/802,152 Page 12

Art Unit: 1634

controlling and maintaining uniform temperature within integrated support (Column 19, lines 1-4) wherein the thermal member is linear (Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the integrated support of Stimpson by embedding a thermal member for maintaining a uniform temperature as taught Lipshutz et al (Column 19, lines 1-4) and as instantly claimed. The thermal member of Lipshutz et al would permit the integrated support used to control and maintain appropriate temperatures while utilizing the integrated support of Stimpson. Therefore, one of ordinary skill would have been motivated to integrate the thermal member of Lipshutz et al into the integrated support of Stimpson for the expected benefits of controlling and maintaining desired temperatures in hybridization applications of Stimpson (Examples 5-6, Column 15, line 37-Column 16, line 30)

Conclusion

- 14. No claim is allowed.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D. Primary Examiner Art Unit: 1634 November 4, 2003